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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/402,488	02/16/2000	MAURICE MOLONEY	9369-98	6010

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EXAMINER	
STEADMAN, DAVID J	
ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/402,488	MOLONEY ET AL.	
	Examiner	Art Unit	
	David J Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2004 and 18 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-10,12-16,18 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-10,12-16,18 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 October 1999* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] Claims 1, 4-10, 12-16, and 18-19 are pending in the application.

[2] Applicant's amendments to the claims, filed October 20, 2004 and December 2, 2004 are acknowledged. These amendments failed to meet the requirements of 37 CFR § 1.121. See Office communications mailed 11/26/2004 and 12/23/2004.

[3] Applicants' amendment to the claims, filed January 18, 2005, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.

[4] Applicant's arguments filed October 20, 2004 have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

[5] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Claim Objections

[6] In view of applicants' amendment, the objection to claims 4, 7, 9-10 and 13-14 for reciting "(c)" is withdrawn.

[7] In view of applicants' amendment, the objection to claim 12 for reciting "gut or the of said animal" is withdrawn. It should be noted that claim 12 is not marked up in accordance with 37 CFR § 1.121 to show changes to the claim. Applicants are advised

to present amendments to the claims in accordance with the requirements of 37 CFR § 1.121.

Claim Rejections - 35 USC § 112, Second Paragraph

[8] The rejection of claim(s) 1, 4-10, 12-16, and 18-19 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "pro-peptide" is maintained for the reasons of record.

RESPONSE TO ARGUMENT: Applicants argue the term has been adequately defined in the specification as being the amino terminal portion of a zymogen or a functional portion thereof up to the maturation site, which is definite and would be understood by a person of skill in the art. Applicants argue the examiner need not further interpret the term.

In a previous Office action, the examiner provided his interpretation of the term "pro-peptide" (see p. 3 of the Office action mailed 4/29/04), which is in accordance with the definition provided in the specification and the provisions of MPEP § 2111. While applicants do not expressly dispute the examiner's interpretation of the term, applicants assert the examiner "does not need to further interpret the claim" and argue that a "Phe within [a] Phe-Met chymosin cleavage site...does not constitute a chymosin-pro-peptide" (see p. 10 of the instant response). In this way, applicants appear to imply that the examiner's interpretation is in error and the term has some meaning that is of a different scope than the examiner's interpretation of the term. However, applicants do not state or elaborate on such an interpretation for the record. In view of applicants'

argument, it remains unclear as to the scope of amino acid sequences that are considered by applicants to be encompassed by the term "pro-peptide." Clarification is requested.

For examination purposes, the examiner has maintained the interpretation of the term "pro-peptide" as a portion (including a single amino acid) of a chymosin pro-peptide that allows cleavage of the fusion protein by an autocatalytically maturing aspartic protease.

Claim Rejections - 35 USC § 112, First Paragraph

[9] The scope of enablement rejection of claims 10 and 16 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue "multiple methods for adding the mature aspartic protease *in vivo* are disclosed in the application," citing 1) recombinant co-expression of chymosin in a host cell expressing the fusion protein; 2)-3) cleavage of the fusion protein under physiological conditions in a target organ, tissue, or bodily fluid with or without the addition of mature chymosin; and 4) cleavage of the fusion protein with red turnip beetle gut extract.

Applicants' argument is not found persuasive. Initially, it is noted that example 4), *i.e.,* cleavage of the fusion protein with red turnip beetle gut extract, is not considered to be addition of chymosin under *in vivo* conditions, but rather *in vitro* conditions. As such, this is not a working example of the claimed invention. Regarding example 1), the examiner has previously indicated that the specification is enabling for this working

example and there is no dispute that this working example is enabled by the specification. Regarding examples 2)-3), the specification fails to provide even a single working example of adding a mature form of chymosin in a mammal for cleavage of the fusion protein in a target organ, tissue, or bodily fluid. Further, the specification fails to provide even a single working example of examples 2)-3) or any specific guidance as to how the fusion protein is to be expressed in the target organ, tissue or bodily fluid, how the mature form of an autocatalytically maturing aspartic protease is to be delivered to the target organ, tissue, or bodily fluid, and guidance as to whether successful cleavage would be achieved. Without such guidance, it is highly unpredictable as to whether the method can be carried out under any *in vivo* conditions as broadly encompassed by the claims. As such, the examiner maintains that the specification fails to enable the full scope of the claimed methods.

[10] The enablement rejection of claims 12 and 18 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue Example 3 of the specification discloses cleavage of a fusion protein with red turnip beetle gut extract. Applicants' argument is not found persuasive.

As noted above, this example is carried out under *in vitro,* not under *in vivo* conditions. As such, this example clearly fails to enable the claimed invention. Even in view of the additional teachings provided in the specification and the prior art, the specification fails to enable the claimed invention at least for the reasons stated above regarding claims 10 and 16.

Claim Rejections - 35 USC § 102

[11] The rejection of claim(s) 1, 4, 6-9, 13, 15, and 19 under 35 U.S.C. 102 (b) as being anticipated by Walsh et al. (J Biotech 45:235-241; cited in the response filed 01/28/04) is maintained for the reasons of record and the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue: 1) the Phe-Leu amino acid junction is a pseudochymosin cleavage site and not a pro-chymosin cleavage site and 2) the Phe-Met chymosin cleavage site of the encoded polypeptide of Walsh et al. does not constitute a chymosin pro-peptide based on a sequence comparison analysis.

Applicants' argument is not found persuasive. In response to argument 1), it is acknowledged that the examiner stated in a previous Office action, "[t]he specification indicates that the cleavage site of a bovine chymosin pro-peptide has the sequence Phe-Leu with Phe being the C-terminal amino acid of the bovine chymosin pro-peptide (page 19, top)." To clarify the record, the specification states that the cleavage site of bovine chymosin pro-peptide actually has the sequence of Phe-Val (page 19, top), not Phe-Leu.

However, in this case, it is immaterial as to whether Phe-Leu is a pseudochymosin or pro-chymosin cleavage site. What is important is that the N-terminal amino acid of the chymosin cleavage site of the fusion protein of Walsh et al. is a Phe (see p. 237). According to the examiner's broad, but reasonable, interpretation of the term pro-peptide, this Phe of the encoded polypeptide of Walsh et al. is considered to be a "functional portion" of a chymosin pro-peptide. Claim 1 recites, "a chimeric nucleic

acid sequence encoding a fusion protein, the chimeric nucleic acid comprising (a) a nucleic acid sequence encoding a chymosin pro-peptide..." In this case, the nucleic acid of Walsh et al. encodes Phe, which is a "functional portion" of a chymosin pro-peptide. Thus, in accordance with the examiner's broad, but reasonable, interpretation of the term "pro-peptide," the method of Walsh et al. anticipates the claims.

In response to argument 2), it is noted that there is no dispute that the kappa-casein peptide encoded by the expression vector of Walsh et al. is not structurally identical to the chymosin pro-peptide as shown at, *e.g.,* Figures 1-2 of the instant application. However, the claims are not so limited to pro-peptides that are identical to the pro-peptide shown in Figures 1-2 of the instant application. Instead, as stated above, the "pro-peptide" can be "a functional portion thereof up to the maturation site." In this case, the functional portion of the chymosin pro-peptide as shown in Figures 1-2 of the instant application is Phe. As stated above, claim 1 recites, "a chimeric nucleic acid sequence encoding a fusion protein, the chimeric nucleic acid comprising (a) a nucleic acid sequence encoding a chymosin pro-peptide..." In this case, the nucleic acid of Walsh et al. encodes a Phe residue at the chymosin cleavage site, which is a "functional portion" of a chymosin pro-peptide. Thus, in accordance with the examiner's broad, but reasonable, interpretation of the term "pro-peptide," the method of Walsh et al. anticipates the claims.

Claim Rejections - 35 USC § 103

[12] The rejection of claim(s) 1, 4, 6-9, 13, 15, and 19 under 35 U.S.C. 103 (a) as being unpatentable over Ward et al. (US Patent 6,265,204 B1) in view of McCaman et al. (J Biol Chem 261:15345-15348; cited in the IDS filed January 29, 2000) is maintained for the reasons of record and the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue that at the time of the invention, one of ordinary skill in the art would not have recognized that a chymosin pro-peptide could be cleaved by the addition of the mature form of an autocatalytically maturing aspartic protease with an expectation of success. Applicants suggest three reasons for a lack of expected success: 1) not knowing whether non-specific cleavage of the heterologous polypeptide would occur with the addition of mature chymosin; 2) whether the addition of chymosin would result in non-precise cleavage; and 3) whether the addition of mature chymosin would be efficient.

Applicants' argument is not found persuasive. In response to applicants' suggested three reasons for a lack of expected success, it is noted that the claims are not so limited to producing a heterologous polypeptide without non-specific or efficient cleavage, only that "the chymosin pro-peptide is cleaved from the fusion protein." Applicants' previous arguments traversing a scope of enablement rejection (see particularly pp. 6-7 of the response filed 9/18/01) appear to be contrary to applicants' arguments in the instant response. Previously, applicants asserted that "the claims do not preclude some non-specific cleavage of the heterologous protein" (p. 6, bottom of the response filed 9/18/01). Further, it is noted that applicants have provided no evidence that their cleavage system will not also generate non-specific or non-precise

cleavage or would be efficient with all fusion proteins and one of ordinary skill in the art at the time of the invention would have recognized that, due to the different conformations of individual proteins, such events would likely have occurred in at least some fusion proteins.

Applicants assert that, while it was known in the art that chymosin could self-cleave, it was not known whether mature chymosin could cleave a chymosin pro-peptide. It should be noted that the claimed method is not so limited to a chymosin pro-peptide being cleaved by chymosin. Instead, the method encompasses cleavage of the pro-peptide by "a mature form of an autocatalytically maturing aspartic protease." In this case, it was well known in the art (see, *e.g.,* Dunn et al.) that a variety of aspartic proteases have the ability to cleave a peptide with Phe at the P1 position. It is noted that applicants' argument appears to indicate that applicants have disclosed an unexpected result, *i.e.,* that mature chymosin, *i.e.,* chymosin free of the pre- and pro-peptides, can cleave its own pro-peptide cleavage site.

In response to this argument, it is noted that "[t]he arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results..." See MPEP § 716.01(c).

Obviousness does not require absolute predictability, however, at least some degree of predictability is required. See MPEP § 2143. Even assuming *arguendo* the claimed method was limited to cleavage of the pro-peptide by chymosin, it is noted that,

as prochymosin autocatalytically cleaves its own pro-peptide, one of ordinary skill in the art at the time of the invention would have recognized that there is at least some degree of predictability that the catalytically active mature form of chymosin would also cleave a pro-peptide present in a fusion protein. Walsh et al. demonstrate that catalytically mature chymosin can cleave a fusion protein comprising a cleavage site of a natural substrate. Similarly, the chymosin pro-peptide cleavage site of Phe-Val is a natural chymosin cleavage site and one of ordinary skill in the art would have had a reasonable expectation of success for cleaving the fusion protein of Ward et al. comprising a chymosin cleavage site with mature chymosin. Also, one of ordinary skill in the art would have recognized that aspartic proteases exhibit variability in the requirement of the amino acid at the P2 position of their respective cleavage sites as evidenced by Dunn et al. Also, as evidenced by Yonezawa et al. (*Int J Pept Protein Res* 47 :56-61), mature chymosin can cleave a peptide comprising a Phe-Leu site (see particularly p. 58, Table 1), which is autocatalytically cleaved by prepro-chymosin, suggesting that mature chymosin has the ability to cleave sites that are cleaved by the zymogenic form of the enzyme. This is further evidenced by Nedjar et al. (*Int J Biochem* 23 :377-381), which teaches that mature chymosin can cleave at a Phe-Val site (see particularly p. 380, Figure 4), which, as stated above, is the pro-peptide cleavage site. In view of the state of the art at the time of the invention, it is the examiner's position that an ordinarily skilled artisan would have had a reasonable expectation of success that a mature form of an autocatalytically maturing aspartic protease, particularly chymosin, would have had the ability to cleave a Phe-Val linker in a fusion protein.

While MPEP § 2143 states, "[e]vidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness," applicants have presented no evidence that one of ordinary skill in the art at the time of the invention would not have a reasonable expectation of success. In previous arguments, applicants asserted an expectation of success for practicing a method encompassing a much broader scope, which included the use of mature chymosin for cleavage of a chymosin pro-peptide, by stating that "one of skill in the art having chosen a particular pro-peptide/heterologous protein combination would be readily able to determine the optimal conditions for the cleavage reactions" and "[s]uch determination of appropriate reaction conditions permitting proteolysis, is part of a routine procedure" (p. 6, bottom of the response filed 9/18/01).

Applicants argue secondary considerations, including long-felt need, must be considered and given due weight. Applicants argue Ward et al. recognizes the difficulties of efficient production and recovery of fusion proteins by teaching that in some embodiments, after cleavage via chemicals or endoproteinases, the desired polypeptides contain unwanted amino acids and that a variety of proteases may be used to remove the undesired amino acids.

Applicants' argument is not found persuasive. As stated above, applicants acknowledge that "the claims do not preclude some non-specific cleavage of the heterologous protein" (p. 6, bottom of the response filed 9/18/01) and applicants have provided no evidence that their cleavage system will not also generate non-specific or non-precise cleavage or would be efficient with all fusion proteins, particularly in view of

the broad substrate specificity of chymosin as evidenced by Yonezawa et al. (*Int J Pept Protein Res* 47 :56-61) and Nedjar et al. (*Int J Biochem* 23 :377-381). Such artifacts are potentially inherent in any fusion protein cleavage system.

Also, it is noted that MPEP § 2141 acknowledges that long felt need "might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquires may have relevancy." However, in view of the prior art as cited above, one of ordinary skill in the art would have recognized that a long felt need would have been satisfied by the prior art teachings.

[13] The rejection of claim(s) 5 under 35 U.S.C. 103 (a) as being unpatentable over Ward et al. in view of McCaman et al. as applied to claims 1, 4, 6-9, 13, 15, and 19 above and further in view of Fine et al. (*Gen Comp Endocrinol* 89:51-61; cited in the Office action mailed December 04, 2001) is maintained for the reasons of record and the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue the deficiencies of Ward et al. and McCaman et al. are not remedied by Fine et al. Applicants argue Fine et al. does not teach or suggest an improved method to prepare cGH by linking the cGH to a pro-peptide of chymosin.

Applicants' argument is not found persuasive. It is the combination of references, not the reference of Fine et al. alone that makes obvious the claimed invention. For the reasons stated above, Ward et al. and McCaman et al. make obvious claim 1, from which claim 5 depends. In view of the teachings of Ward et al., McCaman et al., and

Fine et al., the examiner maintains that the invention of claim 5 would have been obvious to one of ordinary skill in the art at the time of the invention.

[14] The rejection of claim(s) 5 under 35 U.S.C. 103 (a) as being unpatentable over Walsh et al. in view of Fine et al. is maintained for the reasons of record and the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue the deficiencies of Walsh et al. are not remedied by Fine et al. Applicants argue Fine et al. does not teach or suggest an improved method to prepare cGH by linking the cGH to a pro-peptide of chymosin.

Applicants' argument is not found persuasive. It is the combination of references, not the reference of Fine et al. alone that makes obvious the claimed invention. For the reasons stated above, Walsh et al. anticipates claim 1, from which claim 5 depends. In view of the teachings of Walsh et al. and Fine et al., the examiner maintains that the invention of claim 5 would have been obvious to one of ordinary skill in the art at the time of the invention.

[15] The rejection of claim(s) 14 under 35 U.S.C. 103 (a) as being unpatentable over Walsh et al. in view of Dunn et al. OR Ward et al. in view of McCaman et al. as applied to claims 1, 4, 6-9, 13, 15, and 19 above and further in view of Dunn et al. is maintained for the reasons of record and the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue the deficiencies of Walsh et al. or Ward et al. and McCaman are not remedied by Dunn et al. Applicants argue the peptides used in the study of Dunn et al. are synthetic peptides that have "no significant homology to the propeptide of the aspartic proteases" and that an ordinarily skilled

artisan would realize that a synthetic peptide having a Phe residue in the P1 position could be cleaved by a number of aspartic proteases, but this reference in no way teaches that the aspartic proteases would be able to cleave a chymosin pro-peptide.

Applicants' argument is not found persuasive. It appears that applicants are arguing that, based on the teachings of Dunn et al. one of ordinary skill in the art would not have a reasonable expectation of success that the results of Dunn et al., which are generated by using synthetic peptides, would translate into cleavage of full length polypeptides having an identical cleavage site in the fusion linker. Although applicants fail to show the results of their BLAST analysis, their argument that the synthetic peptides have no significant homology to the pro-peptide of the aspartic proteases would tend to support the examiner's assertion that aspartic proteinases other than chymosin can cleave a chymosin pro-peptide. The reference of Dunn et al. demonstrates the promiscuity of aspartic proteases toward other cleavage sites having Phe at the P1 position, including other pro-peptide cleavage sites. The use of synthetic peptides for determining the specificity of an aspartic protease, *e.g.,* chymosin, is well known in the prior art as evidenced by Dunn et al., Yonezawa et al., and Nedjar et al.

As noted above, obviousness does not require absolute predictability, however, at least some degree of predictability is required. See MPEP § 2143. In this case, the results of Dunn et al., using synthetic peptides as a model system, provide a high degree of predictability that non-chymosin aspartic proteinases would have the ability to cleave a chymosin pro-peptide cleavage site. While MPEP § 2143 states, "[e]vidence showing there was no reasonable expectation of success may support a conclusion of

nonobviousness." However, applicants have presented no evidence that one of ordinary skill in the art at the time of the invention would not have a reasonable expectation of success that, based on the teachings of Dunn et al., one would not expect that non-chymosin aspartic proteinases would not have the ability to cleave a chymosin pro-peptide cleavage site.

It is noted that applicants' instant arguments appear to be in conflict with applicants' previous arguments, wherein applicants argued that a chymosin pro-peptide can be cleaved by other aspartic proteases in view of prior art teachings, citing numerous prior art references that were available to a skilled artisan at the time of the invention (see pp. 5-6 of the response filed 2/4/03).

Conclusion

[16] Status of the claims:

- Claims 1, 4-10, 12-16, and 18-19 are pending.
- Claims 1, 4-10, 12-16, and 18-19 are rejected.
- No claim is in condition for allowance.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Thursday and alternate Fridays from 6:30 am to 4:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (571) 272-8300. Draft or informal FAX communications should be directed to (571) 273-0942. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

02-23-05

DAVID J. STEADMAN, PH.D.
PRIMARY EXAMINER